

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:19-cr-00591-ERW-NAB
	)	
ABDUL NAUSHAD, M.D., and	)	
WAJIHA NAUSHAD,	)	
	)	
Defendants.	)	

**GOVERNMENT’S RESPONSE TO DEFENDANTS’  
JOINT MOTION TO DISMISS SECOND SUPERSEDING INDICTMENT**

COMES NOW Carrie Costantin, Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. §515, and Dorothy L. McMurtry, Assistant United States Attorney for the Eastern District of Missouri, and responds to the “Joint Motion to Dismiss Second Superseding Indictment” (“Motion,” Doc. 112) filed by defendants Abdul Naushad, M.D. (“Dr. Naushad”) and Wajiha Naushad (jointly referred to as “Defendants”). For the reasons stated below, the Government urges this Court to deny the Defendants’ Motion.

**Defendants’ Arguments<sup>1</sup>**

In their Motion, the Defendants assert that the Orthovisc they purchased from Canada (“referred to herein as “foreign Orthovisc”) is covered by the existing Premarket Application Approval (“PMA”) submitted by Anika Therapeutics (“Anika”) and subsequently approved by the Food and Drug Administration (“FDA”). Relying on this faulty premise, the Defendants ask

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<sup>1</sup> The Defendants entitle their motion, “Joint Motion to Dismiss Second Superseding Indictment,” and also “incorporate the arguments relating to the adulteration and fraud counts in their motion to dismiss the original indictment.” The Government relies on, and will not repeat in this pleading, its arguments in opposition to the motion to dismiss the original indictment as the Court has previously considered and decided the issues raised in the Defendants’ motion to dismiss the original indictment.

the Court to hold as a matter of law that the foreign Orthovisc is not adulterated, within the meaning of 21 U.S.C. § 351(f)(1)(B). The Defendants further urge dismissal because these same counts do not expressly allege that the PMA for Orthovisc “has been suspended or otherwise is not in effect.” Because of this purported omission, the Defendants contend the counts fail to allege an essential element, which renders the adulteration counts fatally flawed.

Secondly, the Defendants contend that the Indictment is multiplicitous because the misbranding charges in Counts 2-7 and the adulteration charges in Counts 8-13 require proof of the same facts and are brought under the same statute. They ask the Court to order the Government to elect whether it will proceed to trial on the adulteration counts or the misbranding counts.

As demonstrated below, the Defendants’ arguments are wrong and should be rejected. The Government will address each of the arguments separately.

### **The Foreign Orthovisc is “Outside the PMA” and Adulterated**

As stated in earlier pleadings, it is the Government’s position that a determination whether the foreign Orthovisc was FDA approved can only be made after the presentation of evidence at trial. This issue is hotly disputed by the parties and a determination cannot be made before trial. *See e.g., United States v. Browning*, 436 F.3d 780, 781 (7th Cir. 2006) (“[T]here is no summary judgment or directed verdict in a criminal case....”); *United States v. DeLaurentis*, 230 F.3d 659, 661 (3d Cir. 2000) (noting that there is no criminal equivalent to the motion for summary judgment in civil cases).

Determining the legality of the foreign Orthovisc begins against the backdrop of the overall regulation of medical devices under the Food, Drug, and Cosmetics Act (“FDCA”). Devices are classified into one of three categories: Class I (lowest risk), II, or III (highest risk).

*See* 21 U.S.C. § 360c. A device’s class determines the type of regulatory controls necessary to assure the safety and effectiveness of the device and any process it must complete prior to marketing. Generally, “new” devices that come on the market, like the Orthovisc at issue in this case, are automatically classified as Class III as a matter of law. 21 U.S.C. §§ 360c(f)(1) and 360e(a).<sup>2</sup>

Class III devices are those for which neither “general” nor “special” controls would provide reasonable assurance of safety and effectiveness and which are intended for use in supporting or sustaining life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). Class III devices receive “the most federal oversight” and are subject to “rigorous” premarket review and approval requirements through the PMA process. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008); *see also* 21 U.S.C. § 360e (describing PMA requirements for Class III devices). A device is adulterated for purposes of the FDCA if it is a Class III device, is not exempt from the requirement of FDA approval, and has not received FDA approval. *See* 21 U.S.C. § 351(f)(1); *Riegel*, 552 U.S. at 317.

The purpose of a PMA for a Class III device is to provide FDA with sufficient information to demonstrate that there is a reasonable assurance that the device is safe and effective under the conditions of use in the proposed labeling. 21 U.S.C. § 360e(d). Before granting PMA approval, FDA must find that: (1) there is a reasonable assurance that the device is safe and effective for each of its labeled conditions of use; (2) the device was manufactured in

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<sup>2</sup> The only way a manufacturer can remove a new device from the automatic, statutory Class III designation, and thereby avoid the premarket approval process is to obtain an order from the FDA, reclassifying the device into Class I or II (see 21 C.F.R. Part 860, Subpart C-Reclassification), or an order finding the new device “substantially equivalent” to a legally marketed (“predicate”) device that does not require premarket approval. 21 U.S.C. § 360c(f); 21 C.F.R. §§ 807.92 and 807.100.

compliance with the quality system regulations in 21 C.F.R. part 820; (3) the proposed labeling is not false or misleading in any particular; and (4) the device conforms in all respects to any applicable performance standards. 21 U.S.C. § 360e(d)(2).

A PMA must contain information about the device, including its indications for use, a description of how the device functions and its physical and performance characteristics, a summary of any animal and clinical (human) studies conducted with the device, and an explanation of how the data and information in the application constitute valid scientific evidence of safety and effectiveness of the device for its intended use and otherwise satisfy the statutory requirements. 21 U.S.C. § 360e; 21 C.F.R. part 814, Subpart B. A PMA must also include a complete description of the methods used in, and the facilities and controls used for the manufacture, packing, and storage of the devices, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device. *See* 21 U.S.C. § 360e(c)(1)(C) and 21 C.F.R. § 814.20(b)(4)(v).

FDA scientists evaluate the data and information in the PMA, including performance and design specifications, information relating to the method of manufacture, labeling, and indications for use, among other things. *See* 21 C.F.R. § 814.20. FDA's review process for a PMA is, thus, thorough and scientifically rigorous. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

FDA grants PMA approval only upon a finding that the PMA contains sufficient valid scientific evidence, as defined under 21 C.F.R. § 860.7, of safety and effectiveness. Approval of a PMA represents FDA's determination, based on its thorough expert review of the voluminous data and information in the PMA and any other information deemed pertinent by the FDA, that

there is a reasonable assurance that the device is safe and effective under the conditions set forth in the labeling. 21 U.S.C. § 360e(d). It means, further, that the FDA has determined that the proposed labeling for the device complies with the detailed labeling requirements set forth in 21 C.F.R. parts 801 and 809, and that the labeling is neither false nor misleading. *See* 21 U.S.C. § 360e(d); 21 C.F.R. § 814.45.

Following FDA's premarket approval, a manufacturer generally must submit a supplemental application to FDA and receive its approval before making any changes to a device that affect its safety or effectiveness.<sup>3</sup> *See* 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(a). The same process that applies to an original PMA application generally applies to a supplemental application. *See* 21 U.S.C. § 360e(d)(6)(B); 21 C.F.R. § 814.39(c); *Riegel*, 552 U.S. at 319. With only narrow exceptions, the manufacturer also must receive FDA's approval before making any changes to the labeling of a device. *See* 21 U.S.C. § 360e(d)(6); 21 C.F.R. 814.39(a) and (d)(1).

In this case, the foreign Orthovisc devices, when originally manufactured by Anika, were not intended to be distributed in the United States. Instead, the foreign Orthovisc devices were originally manufactured and labeled for foreign markets by Anika, the same manufacturer that obtained the PMA for the Orthovisc approved for distribution in the United States.

Nonetheless, the Defendants rely on the erroneous presumption that the foreign Orthovisc devices themselves are the same as the FDA-approved Orthovisc devices. However, as stated above, the "rigorous" PMA approval process encompasses far more than approval of the physical

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<sup>3</sup> Manufacturers are also required to collect and report to FDA information on certain adverse events related to the device after it has been approved. *See* 21 U.S.C. § 360i(a); 21 C.F.R. Pt. 803. A device manufacturer is also required to provide periodic reports to FDA. *See* 21 C.F.R. § 814.84. Among other things, a periodic report must identify any reports in the scientific literature about the device, as well as any unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device about which the manufacturer knows or reasonably should know. *See* 21 C.F.R. § 814.84(b)(2). Based on new information reported to FDA or other information known to the agency, FDA may withdraw premarket approval of a Class III medical device if it finds, among other things, that the device no longer satisfies the standards for premarket approval. 21 U.S.C. § 360e(e)(1).

device itself. *See Riegel*, 552 U.S. at 317-19 (noting that the FDA spends an average of 1,200 hours reviewing each PMA application, including review of the proposed labeling and the facilities used to manufacture the device) (citations omitted). As recognized by the Supreme Court, “the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.” *Id.* at 323.

When a device deviates from the specifications of the approved PMA, it is no longer the “approved” device – *i.e.*, it falls “outside the PMA.” *Cf. United States v. Genendo*, 485 F.3d 958, 961-62 (7th Cir. 2007) (noting that foreign-market drugs with the same chemical composition as the FDA-approved, U.S.-market drugs and originally manufactured in the same facility as the FDA-approved drugs were nevertheless unapproved new drugs under the FDCA because, in part, they were repackaged in a facility that was not listed in the approved new drug application and the labeling differed from the FDA-approved labeling); *In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 790 (8th Cir. 2006) (“Because foreign labeling differs from domestic labeling, approval granted to a particular manufacturer for a particular [drug] to be distributed in the United States does not constitute approval of another drug—even one with the same chemical composition—to be distributed in Canada with different labeling, and then imported into the United States”). The legal and practical effect of a Class III device falling “outside the PMA” is that the device is not PMA-approved, and thus, is adulterated under the FDCA. *See* 21 U.S.C. § 351(f)(1). *Cf. In re Canadian Import Antitrust Litigation*, 470 F.3d at 790 (recognizing that the parallel FDA approval process for drugs reflected Congressional intent to create a “closed system” to “ensure that approved prescription drugs are ‘subject to FDA oversight’ and are

‘continuously under the custody of a U.S. manufacturer or authorized distributor,’ thus helping to ensure that the quality of drugs used by American consumers is consistent and predictable”), citing *United States v. Rx Depot, Inc.*, 290 F.Supp.2d 1238, 1241–42 (N.D. Okla. 2003).

The foreign Orthovisc in this case deviates from the FDA-approved PMA in several significant respects: (1) the labeling differs from the current FDA-approved labeling for Orthovisc, *see* 21 U.S.C. § 360e(c)(1)(F); 21 C.F.R. §§ 814.20(b)(10) and 814.39(a)(2) and (2); the labeling failed to include warnings contained in the FDA-approved labeling, including a warning not to use certain substances on the skin prior to administration of the Orthovisc; advice not to freeze the Orthovisc and to store it at room temperature; information concerning the safety and effectiveness of Orthovisc in pregnant women and children; and information about the effects of the Orthovisc on patients. Additionally, the labeling on foreign Orthovisc failed to limit use of the device to the knee joint, which is the only current indication for use approved by the FDA.

The above information, and other labeling information approved by FDA, was not on the labeling of the foreign Orthovisc. Accordingly, the foreign Orthovisc falls “outside the PMA” for the U.S.-market devices, does not have its own PMA approval (a statutory requirement for Class III devices), and is adulterated. *See* 21 U.S.C. §§ 351(f)(1)(B) and 360e(a).

### **Counts 8-13 Allege All Essential Elements**

The Defendants also argue that Counts 8-13 do not allege a crime. They contend that to validly charge “adulteration” under 21 U.S. C. 351(f)(1)(B), the PMA for the FDA-approved Orthovisc had to be suspended or otherwise not in effect. The defendants further argue that the adulteration counts fail to allege either theory and thus do not allege a crime. There are several problems with the Defendants’ argument.

First, the Eighth Circuit Court has held that an “indictment will ordinarily be held sufficient unless it is so defective that it cannot be said, by any reasonable construction, to charge the offense for which the defendant was convicted.” *United States v. Mann*, 701 F.3d 274, 288 (8th Cir. 2012), *quoting United States v. Sewell*, 513 F.3d 820, 821 (8th Cir. 2008); *see also United States v. Hernandez*, 299 F.3d 984, 992 (8th Cir. 2002). “It is generally sufficient that an indictment set forth the offense in the words of the statute itself, as long as ‘those words themselves fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offence intended to be punished.’” *United States v. Nabors*, 45 F.3d 238, 240 (8th Cir. 1995) (citations omitted).

Counts 8-13 fully meet and exceed the sufficiency requirement defined by the above cases. Paragraph 50 of Counts 8-13 tracks the language of 21 U.S.C. § 331(c) and alleges that the Defendants, “with the intent to defraud and mislead, did receive, and caused to be received, in interstate commerce and did deliver and proffer, and caused to be delivered, for pay or otherwise an adulterated device, specifically non-FDA approved Orthovisc, that was adulterated within the meaning of 21 U.S. C. 351(f)(1)(B).” Although the language of 21 U.S. C. § 351(f)(1)(B) was not quoted in paragraph 50, the citation to Section 351(f)(1)(B) gave the Defendants notice that the adulteration counts were based on the lack of a required PMA. Further, paragraph 26, expressly incorporated by reference in Counts 8-13, alleged: “This non-FDA approved Orthovisc or foreign Orthovisc has not been approved by the FDA, and as a result, the device’s safety and efficacy are unknown.”

Contrary to the Defendants’ argument, 21 U.S. C. 351(f)(1)(B) contains no requirement that a PMA must first exist before there can be a charge of adulteration; the Defendants cite no authority in support of their argument. Moreover, it defies logic that Congress, in passing Section

351(f)(1)(B) in the first instance, and the FDA, in regulating Class III medical devices, would consider a device adulterated when a previously approved PMA for a device had been suspended but would not consider a Class III device adulterated when no PMA for the device was ever applied for or was ever in effect.

### **Misbranding and Adulteration Counts Are Not Multiplicitous**

The Defendants argue that the misbranding offenses charged in Counts 2-7 and the adulteration offenses charged in Counts 8-13 are multiplicitous because evidence concerning labeling will be offered as proof of both the adulteration and misbranding charges. The Defendants wrongly interpret the test for determining whether an indictment is multiplicitous.

A multiplicitous indictment is one that charges a single offense in multiple counts. *See, e.g., United States v. Worthon*, 315 F.3d 980, 983 (8th Cir. 2003). The danger of multiplicity is that it may lead to a defendant receiving multiple punishments for a single offense. *United States v. Roy*, 408 F.3d 484, 492 (8th Cir. 2005). In this manner, multiplicity violates the Fifth Amendment's Double Jeopardy Clause, which "protects against multiple punishments for the same offense." *United States v. Hinkeldey*, 626 F.3d 1010, 1013 (8th Cir. 2010) (citations omitted).

The test to determine whether a violation of two different statutory provisions constitutes the same offense is set forth in *Blockburger v. United States*, 284 U.S. 299, 304 (1932). The *Blockburger* test embodies the presumption that Congress "ordinarily does not intend to punish the same offense under two different statutes." *Whalen v. United States*, 445 U.S. 684, 691-92 (1980).

The analysis under *Blockburger* is straightforward: "Where the same act or transaction constitutes a violation of two distinct statutory provisions, the test to be applied to determine

whether there are two offenses or only one is whether each [statutory] provision requires proof of an additional fact which the other does not.” *Blockburger*, 284 U.S. at 304; *see also Rutledge v. United States*, 517 U.S. 292, 297 (1996). “Put another way, the *Blockburger* test asks whether each offense contains an element not contained in the other; if not, they are the ‘same offense’ and punishment for both crimes violates double jeopardy.” *Id.*

The Eighth Circuit has emphasized that the “*Blockburger* test focuses on the statutory elements of the offenses, rather than the evidence presented at trial.” *United States v. Sandstrom*, 594 F.3d 634, 654 (8th Cir. 2010); *see also United States v. Hansen*, 944 F.3d 718,724 (8th Cir. 2019) (*Blockburger* test “is concerned solely with the statutory elements of the offenses charged.”)

The Sixth Circuit similarly stated: “The Court focuses on the statutory elements of the two crimes . . . offered or relied upon to secure a conviction . . . if each [offense] requires proof of a fact that the other does not, the *Blockburger* test is satisfied, notwithstanding a substantial overlap in proof offered to establish the crimes.” *United States v. Barrett*, 933 F.2d 355, 360-61 (6<sup>th</sup> Cir. 1991), *citing Iannelli v. United State*, 420 U.S. 770, 785 n.17 (1975); *see also United States v. Boldin*, 772 F.2d 719, 726 (11th Cir. 1985) (“*Blockburger* test is applied by analysis of elements of the offense charged, not by focusing on evidence advanced at trial.”) (opinion modified on other grounds in *United States v. Boldin*, 779 F.2d 618 (11th Cir. 1986).

In the present case, the adulteration charges in Counts 8-13 and the misbranding charges in Counts 2-7 require the Government to prove as to each count the following elements: (1) the foreign Orthovisc was a device; (2) the Defendants received the Orthovisc in interstate commerce and delivered and proffered, or caused to be delivered and proffered, the device for pay or otherwise; and (3) the Defendants acted with the intent to defraud and mislead.

Thereafter, the elements diverge for adulteration and misbranding offenses.

The misbranding offenses, as charged in counts 2-7, require the Government to prove that the labeling failed to bear adequate directions for use and adequate warnings, which facts are not necessary to prove the adulteration charges. By contrast, the adulteration offenses, as charged in Counts 8-13, require proof that the foreign Orthovisc did not have an approved PMA, whereas the misbranding charge does not require proof of this element. Thus, the *Blockburger* test is satisfied.

To prove the misbranding counts, as alleged in Counts 2-7, the Government must prove that the foreign Orthovisc, a prescription device, did not bear adequate directions for use and adequate warnings. A prescription device is a device which, because of its potential for harmful effects, methods of use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to direct the use of such device. *See* 21 C.F.R. § 801.109. Because adequate directions for use by a layman cannot be written for prescription devices, they are presumptively misbranded under Title 21, United States Code, Section 352(f)(1). *See United States v. An Article of Device ... Toftness Radiation Detector*, 731 F.2d 1253, 1261 (7th Cir.) (prescription devices presumptively misbranded under 21 U.S.C. § 352(f)(1); burden is on the manufacturer to prove that exemption applies), *cert. denied*, 469 U.S. 882 (1984).

To allow for their lawful movement in interstate commerce, prescription devices are exempt from the adequate-directions-for-use requirement, but only if they meet all the conditions set out in 21 C.F.R. § 801.109. One such condition requires that: “Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any

relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended . . .” *Id.* at § 801.109(c).

Here, the labeling on the foreign Orthovisc did not contain the information required by 21 C.F.R. § 801.109. Absent from the labeling on the foreign Orthovisc was required information, including but not limited to certain “contraindications, side effects, and precautions.” Thus, the foreign Orthovisc did not meet the Title 21, Code of Federal Regulations, Section 801.109 exemption from the requirement to bear adequate directions for use and is misbranded.

The Defendants also argue that the adulteration and misbranding counts are multiplicitous because both are charged under 21 U.S.C. § 331(c), which renders unlawful “[t]he receipt in interstate commerce of any . . . device. . . that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.” When faced with a similar challenge to 21 U.S.C. §331(k), the Eighth Circuit held that Section 331(k), barring adulteration and misbranding of products held for sale, clearly proscribed two distinct and separate crimes. *United States v. Jamieson Pharmaceuticals, Inc.*, 851 F.2d. 532, 546-47 (8th Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982). The Eighth Circuit held that *Blockburger* was not violated because proof of adulteration was established by evidence of non-compliance with good manufacturing practices and proof of the misbranding was established by evidence of alteration of the labels, rendering them false and misleading. *Id.*; *see also United States v. Beech-Nut Nutrition Corp.*, 659 F. Supp. 1487, 1496 (E.D.N.Y. 1987) (holding one shipment of adulterated and misbranded apple juice introduced into interstate commerce may be charged as two separate offenses under 21 U.S.C. §331(a) and no multiplicity because each required proof of facts not necessary to prove the other).

Lastly, the Defendants urge this Court to require the Government to elect between the adulteration and misbranding charges. “Although in a rare case [the risk of a prejudicial compromise verdict] might justify requiring the government to elect among or consolidate counts at trial, it does not justify dismissing well-pleaded counts in an indictment.” *United States v. Webber*, 255 F.3d 523, 527 (8th Cir. 2001) (firearms case). Although the Court has the discretion to order election, the Government should not be required before trial to elect between allegedly multiplicitous charges. *United States v. Platter*, 514 F. 3d 782, 788 (8th Cir. 2008).

### **Conclusion**

For the reasons discussed above, the Government respectfully urges the Court to deny the Defendants’ motion to dismiss the second superseding indictment.

Respectfully submitted,

CARRIE COSTANTIN  
Attorney for the United States Attorney  
Acting Under Authority  
Conferred by 28 U.S.C. § 515

/s/ Dorothy L. McMurtry  
DOROTHY L. McMURTRY, #37727MO  
Assistant United States Attorney  
111 South 10th Street, Room 20.333  
St. Louis, Missouri 63102  
[dorothy.mcmurtry@usdoj.gov](mailto:dorothy.mcmurtry@usdoj.gov)  
(314) 539-2200

**CERTIFICATE OF SERVICE**

I hereby certify that on October 5, 2020, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon all counsel of record.

/s/ Dorothy L. McMurtry  
DOROTHY L. McMURTRY, # 37727MO